DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on 4/21/2008. It is noted that the claim amendments filed on 4/21/2008 have been entered into record. Claims 1-84, 86, 89-90 have been cancelled. Claims 85, 87-88 are pending. Claim 85 has been amended. Claims 85, 87-88 are examined herein.

Applicant's arguments have been fully considered and found persuasive to withdraw the 103(a) obviousness rejection over Lidsky (US Patent 5,602,150) in view of Vetulani (Review Drug Addiction. Part III. Pharmacotherapy of Addiction, Polish Journal of Pharmacology, 2001, vol. 53, pp. 415-434) and Bormann et al. (US Patent 5,061,703) and Decollogne et al. (NMDA Receptor Complex Blockade by Oral Administration of Magnesium: Comparison with MK-801, 1977, Pharmacology Biochemistry and Behavior, vol. 58, no. 1, pp. 261-268). A more detailed explanation is discussed in the Reasons for Allowance section found below.

The terminal disclaimers filed on 6/27/2008 and 7/7/2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patents 6,391,922; 6,689,816; and 6,294,583 have been reviewed and are accepted. The terminal disclaimers have been recorded.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Marc T. Morley on June 30, 2008.

The application has been amended as follows:

In claim 85, after "wherein the ratio of acamprosate to the" please delete "inorganic magnesium salt or chelate is between 1:1 and 6:1 by weight" and add "magnesium in said inorganic magnesium salt or chelate is between 1:1 and 6:1 by weight, and wherein the acamprosate and magnesium salt or chelate of magnesium are in a therapeutically effective amount for alleviating involuntary movement of tardive dyskinesia".

Please delete claim 87.

Please add claim 91, which recites "The pharmaceutical composition of Claim 85, wherein the composition comprises an inorganic salt of magnesium."

Please add claim 92, which recites "The pharmaceutical composition of Claim 85, wherein the composition comprises a chelate of magnesium."

Please add claim 93, which recites "The pharmaceutical composition of Claim 85, wherein the acamprosate is in an amount of 333 mg to 666 mg."

Please add claim 94, which recites "The pharmaceutical composition of Claim 85, wherein the acamprosate is in an amount of 333 mg."

Please add claim 95, which recites "The pharmaceutical composition of Claim 85, wherein the acamprosate is in an amount of 666 mg."

The following is an examiner's statement of reasons for allowance:

The closest prior art is the combination of Lidsky (US Patent 5,602,150) in view of Vetulani (Review Drug Addiction. Part III. Pharmacotherapy of Addiction, Polish Journal of Pharmacology, 2001, vol. 53, pp. 415-434) and Bormann et al. (US Patent 5,061,703) and Decollogne et al. (NMDA Receptor Complex Blockade by Oral Administration of Magnesium: Comparison with MK-801, 1977, Pharmacology Biochemistry and Behavior, vol. 58, no. 1, pp. 261-268), which rejected the claims based on a prima facie case of obviousness.

The Applicant has submitted a Declaration filed on 7/30/2007 showing unexpected results for the combination of acamprosate and magnesium in the treatment of a patient suffering from movement disorders, including Tardive Dyskinesia. This showing of secondary consideration by the Applicant is commensurate with the scope of the claims and sufficient enough to overcome the prima facie case of obviousness. The fact pattern is as follows:

Applicant has never seen any improvement in Tardive Dyskinesia from magnesium alone, nor has it been reported from the patients.

In one case, magnesium was administered to a man with a simple tic of the neck. No improvement in the frequency or the severity of the tic was observed.

Administration of acamprosate to that man resulted to significant reduction in frequency and severity of the tic. About one hour after each dose of acamprosate, the tics would stop and recur after another 3-4 hours.

When magnesium was given in addition to the acamprosate, the usual tic-free period after each acamprosate dose, increased from 3-4 hours to 5-6 hours.

Similarly, acamprosate with magnesium is more effective than acamprosate alone in the treatment of Tardive Dyskinesia.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax

phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Yong S Chong/
Patent Examiner
Art Unit 1617

YSC